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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,723	12/15/2005	Richard Einstein	BJS-3665-166	5102

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EXAMINER	
AEDER, SEAN E	
ART UNIT	**PAPER NUMBER**
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,723	EINSTEIN ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *4-15,18-31 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,16,17,32 and 33* is/are rejected.

7)☒ Claim(s) *1-3,16,17,32 and 33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/15/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The Election filed 1/22/07 in response to the Office Action of 12/20/06 is acknowledged and has been entered. Applicant elected group I and SEQ ID NO:92 with traverse.

The restricted claims were drawn to sequences of SEQ ID NOs: 1-73, 175, 177, 179, and 181. The restriction requirement of 12/20/06 demonstrated that the pending claims were not a contribution over the prior art since sequences of SEQ ID NO:1 were shown to be taught in the prior art. In response to the Office Action of 12/20/06, Applicant amended the claims by deleting claims drawn to SEQ ID NO:1. In the Election filed 1/22/07, Applicant argues the restriction/lack of unity requirement is inappropriate since the amended claims relate to a common special technical feature which defines a contribution over the art cited in the Office Action of 12/20/06. This is not found persuasive. As demonstrated below (see 35 U.S.C. 102(e) rejection below), the elected polynucleotide of group I drawn to SEQ ID NO:92, fragments, and variants thereof does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Claims 1-34 are pending.

Claims 4-15, 18-31, and 34 are withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to a non-elected invention.

Claims 1-3, 16, 17, 32, and 33 are currently under consideration.

Claim Objections

Claims 1-3, 16, 17, 32, and 33 are objected to for being drawn to unelected inventions. Claims 1-3, 16, 17, 32, and 33 are drawn to unelected inventions comprising polynucleotide sequences of SEQ ID NO:2 to 91, 93 to 173, 175, 177, 179, and 181. As noted in the Office Action of 12/20/06, each SEQ ID NO represents a separate invention and *not* a species. Proper correction is required.

Claim 3 is objected to for reciting: "A primer mixture that comprises primers that result in the specific amplification of one of the nucleic acid sequences of Claim 1". One of skill would recognize that primers do not "result in" specific amplification; rather, primers "specifically amplify". It is suspected Applicant intended claim 3 to recite: "A primer mixture that comprises primers that ~~**result in the specific amplification of**~~ **specifically amplify** one of the nucleic acid sequences of Claim 1". Proper correction is required.

Claim 32 and dependent claim 33 are objected to for being drawn to an unelected invention. Claims 32 and dependent claim 33 encompass polypeptides of unelected group IV. Proper correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 16, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 and dependent claims 3, 16, and 17 are rejected because claims 1 and 2 recite the limitation "the nucleic acid sequence" contained in SEQ ID NO:92. There is insufficient antecedent basis for this limitation in the claims. SEQ ID NO:92 "contains" many nucleic sequences. It is unclear which sequence is *the* nucleic acid sequence contained in SEQ ID NO:92.

Claim 16 is rejected for reciting the limitation "a DNA according to Claim 1". There is insufficient antecedent basis for this limitation in the claim. Claim 1 is drawn to nucleic acid sequence. There is no mention of "DNA" in claim 1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 16, 17, 32, and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are

inclusive of: (1) a genus of nucleic acid sequences contained in SEQ ID NO:92, (2) a genus of variants of SEQ ID NO:92 wherein such variants have a nucleic acid sequence that is at least 70% identical to SEQ ID NO:92 when aligned without allowing for gaps, (3) a genus of fragments of SEQ ID NO:92 having a size of at least 20 nucleotides in length, (4) a genus of fragments of variants of SEQ ID NO:92 wherein such variants have a nucleic acid sequence that is at least 70% identical to SEQ ID NO:92 when aligned without allowing for gaps having a size of at least 20 nucleotides in length, (5) a genus of primer mixtures that specifically amplify nucleic acid sequences contained in SEQ ID NO:92, (6) a genus of primer mixtures that specifically amplify variants of SEQ ID NO:92 wherein such variants have a nucleic acid sequence that is at least 70% identical to SEQ ID NO:92 when aligned without allowing for gaps, (7) a genus of primer mixtures that specifically amplify fragments of SEQ ID NO:92 having a size of at least 20 nucleotides in length, (8) a genus of primer mixtures that specifically amplify fragments of variants of SEQ ID NO:92 wherein such variants have a nucleic acid sequence that is at least 70% identical to SEQ ID NO:92 when aligned without allowing for gaps having a size of at least 20 nucleotides in length, and (9) a genus of nucleic acid molecules comprising fragments of SEQ ID NO:92 that encode polypeptides having 8 to 100 amino acids in length. However, the written description in this case only sets forth polynucleotide sequences comprising *the* sequence set-forth in SEQ ID NO:92 (see Figure 2, in particular). The specification does not disclose any other fragment or variant of SEQ ID NO:92 as broadly encompassed in the claims. Further, it does not appear that the specification discloses any primer mixtures.

The state of the art is that sequences comprising *the* sequence set forth in SEQ ID NO:92 have not been disclosed in the art. However, a few variants and fragments thereof, such as a sequence taught by Gish et al (US 2007/0014801 A1; filed 10/12/01) (see below), can be found in the prior art. In regards to the genera of primer mixtures, the broad genus of primer mixtures that would specifically amplify all of the broadly recited sequences are not found in the art. However, a few primer mixtures, such as the primer mixtures taught by Gish et al (see below), can be found in the prior art.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common to that genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d, 2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genera. That is, the specification provides neither a representative number of nucleic acid sequences or primer mixtures that encompass the genera nor

does it provide a description of structural features that are common to the genera. Further, it is noted that expression of a nucleic acid sequence by human prostate cancer cells is not a function of said nucleic acid sequence (see claim 1). Further, in regards to genera encompassing variants and fragments, Applicant is directed to Example 13 of the Synopsis of Application of Written Description Guidelines (http://www.uspto.gov/web/menu/written.pdf), which addresses claims drawn to a genus of polypeptide variants. Example 13 states that even when a specification discloses that changes which produce variants are routinely done in the art, the specification and the claims do not provide any guidance as to precisely what changes should be made. Structural features that could distinguish the compounds of the claimed genera from others not encompassed by the genera are missing from the disclosure. No common structural attributes identify the members of the genera of variants. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is needed. Since the disclosure fails to describe common structural attributes that identify members of the genera, and because the genera are highly variant, the disclosure of SEQ ID NO:92 is insufficient to describe the genera. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genera as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the

'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genera, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolation. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 16, 17, 32, and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Gish et al (US 2007/0014801 A1; filed 10/12/01).

Gish et al teaches a nucleic acid sequence that is expressed by human prostate cancer cells, SEQ ID NO:271, which is a 1365 nucleotide variant of instant SEQ ID NO:92 that is >99% identical to a 1365 nucleotide fragment of instant SEQ ID NO:92 (see paragraph 7 and attached sequence comparison, in particular). It is further noted that SEQ ID NO:271 comprises fragments of instant SEQ ID NO:92 greater than 20 nucleotides in length. It is further noted that SEQ ID NO:271 is a variant of a nucleic acid sequence contained in SEQ ID NO:92 that is at least 70% identical to a nucleic acid sequence contained in SEQ ID NO:92 when aligned without allowing for gaps. Gish et al further teaches a primer mixture comprising primers that specifically amplify SEQ ID NO:271 (see paragraph 190, in particular). Gish et al further teaches a diagnostic kit comprising SEQ I DNO:271, a detectable label, and primers that would specifically amplify a polynucleotide comprising SEQ ID NO:271 (see paragraphs 13, 30-32, and 190, in particular). Further, the specification discloses that instant SEQ ID NO:92 is expressed on the extracellular region of a protein (page 11 of the specification, in particular). Therefore, the sequence taught by Gish et al, which comprises sequences encoding 8 to 100 amino acids in length (see sequence comparison), encodes a polypeptide comprising the sequence of an extracellular domain of a protein encoded by instant SEQ ID NO:92.

Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

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